

Attachment #1 - Frequently asked questions of the DNA Molecular MTB/Rifampin Resistance Assay.

1. Is Rifampin the only drug screen on the panel of this new assay? **Yes, at this time.**
2. What is the turnaround time for this new assay? **12-24 hours after specimen receipt.**
3. Will this test replace the current rRNA Rapid Nucleic Acid Amplification Test (NAAT) for MTB on respiratory specimens? **Yes. This new assay is slightly faster and is based on DNA detection of MTB in addition to offering a single Rifampin drug resistance screen.**
4. What types of clinical specimens are suitable for this new assay? **Sputum and other respiratory tract specimens, such as bronchial washings are acceptable for the new assay.**
5. Will specimen collection and submission be the same for sputum and other clinical respiratory specimens? **Yes.**
6. Will this new assay be run on every respiratory specimen that is submitted for TB analysis? **No, not routinely. AFB smear Positive tests will be automatically reflexed to this new assay.**
****However, providers should immediately contact EPI TB Control Program (502-564-4276) to request this new assay on patients that are clinically high risk.**
7. Will the requisition form for this new assay be the same? **Yes, this new assay does not require separate or different requisition forms.**
8. Will traditional culture and drug susceptibility testing still be performed? **Yes. The current algorithm for culturing and performing drug susceptibility tests remains the same.**
9. May I still submit an AFB smear positive culture- isolate to the state laboratory? **Yes. The state public health lab will run a different protocol for the analysis of the isolate, which may include another type of molecular testing.**
10. Is this test applicable for patients previously treated for MTB? **Test results might be affected by antecedent or concurrent antibiotic therapy. Therefore, therapeutic success or failure cannot be assessed using this test because DNA might persist following antimicrobial therapy. Previous NAAT MTB testing was validated for testing only if patient has been off anti-tuberculosis medication for 1 year and anti-tuberculosis therapy has been initiated for less than 7 days.**
11. How will the lab report reflect the new assay findings? **The lab report will indicate the presence or absence of DNA MTB detection. If DNA MTB is detected, the report will show the results of the Rifampin drug resistance Screen for the rpoB mutations. Both results will be reported at the same time within 12-24 hours after specimen receipt.**